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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,189	12/06/2001	Thomas W. Konowalchuk	LFT000 CIP1	6744

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Steven C. Petersen
Hogan & Hartson, LLP
Suite 1500
1200 17th Street
Denver, CO 80202

EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	12

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,189	Applicant(s) KONOWALCHUK ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2003 has been entered.

Claims 1-33 are pending.

The outstanding rejection under 35 USC 112, first paragraph with regard to new matter is withdrawn in view of the amendments filed April 7, 2003.

Upon consideration of applicant's remarks filed April 7, 2003, the rejection under 35 USC 112, second paragraph is withdrawn.

Upon reconsideration, Examiner reapplies the Pamukoff reference in the rejction under 35 USC 103(a), which is used in the office action mailed February 12, 2002, since it reads on certain limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US Patent 5,385,938) in view of Poli et al. (Food Chemistry, 1979; 4(3): 251-258, reference of record), Wenninger (International Cosmetic Ingredient Dictionary and Handbook, 7th ed., Vol. 1, page 163-168), Merck Index (11th ed., 1989, Glycolic acid monograph 4394, page 4399), and Pamukoff, reference of record.

Yu et al. teaches a topical composition with glycolic acid is the active and about 12.4% ethanol as solvent (See col. 14, Example 1). Yu et al. also teaches that the composition has pH of 3.0 (See col. 14, Example 1). Yu et al. also teaches that the glycolic acid composition is useful to eradicate lesions such as warts, which is a viral infection of papallomas virus (See col. 30, line 10 – col. 31, line 2). Yu et al. also teaches that other pharmaceutically acceptable vehicles other than water and ethanol may be used (See col. 13, lines 11-13). Yu et al. also teaches that the concentration of hydroxyacids, including glycolic acid, may range from 0.02 to 12M (See col. 13, lines 17-19). Yu et al. also teaches that the composition may be formulated into gel, ointment, cream, lotion, and other cosmetic and pharmaceutical preparation (See col. 13, lines 4-6).

Yu et al. does not expressly teach 1,3-butanediol, as known as butylenes glycol, is useful as pharmaceutical vehicle. Yu et al. does not expressly teach that the glycolic acid containing topical composition as useful in inactivating lesions caused by viruses within the Herpesvirdae. Yu et al. does not expressly teach the composition having a specific pH of 2.45.

Poli et al. teaches that glycolic acid is virucidal against herpevirus, orthomyxovirus (influenza virus), and Rhabdovirus (See particularly page 253, Table 1).

Wenninger teaches that butylenes glycol as useful as solvent in numerous cosmetic marketed products (See page 163-168).

Merck Index teaches that the pH 0.5% of glycolic acid solution as 2.50 (See the glycolic acid monograph). Examiner notes that 0.5% of glycolic acid is about 0.31M.

Pamukoff teaches that 1-10% ethyl alcohol containing composition for treating viral infections broadly, in particularly the infections that are caused by Herpes virus such as Herpes Simplex 1, Herpes Simplex 2, and common cold viruses (See particularly page 2, first paragraph; also page 7-9, Examples 2-5; also claims 1 and 2). Pamukoff also teaches that this antiviral composition can be formulated into creams (See particularly page 2, line 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ butylenes glycol as solvent in the topical wart-treating composition of Yu et al. and adjust the pH to 2.45 and use it to inactivate the same viruses. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the glycolic acid containing topical composition, in the herein claimed concentration, in the inactivation of viruses belong to the Herpesvirdae family.

One of ordinary skill in the art would have been motivated to employ butylenes glycol as solvent in the topical wart-treating composition of Yu et al. and adjust the pH to 2.45. Butylenes glycol is known to be useful in cosmetic products as solvent.

Employing any known solvents, including butylene glycol, into a topical composition would have been reasonably expected to be useful in formulating a topical wart-treating composition and using it to activate the same viruses. Moreover, the optimization of result effect parameters (e.g., pH of the composition and the amount of active (glycolic acid)) is obvious as being within the skill of the artisan based on the teaching of Merck Index, absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to employ the glycolic acid containing topical composition to inactivate viruses of the Herpesvirdae family. Based on the teachings of Poli et al. and Yu et al., glycolic acid is known to be effective in killing herpes virus. Therefore, applying a glycolic acid composition would have been reasonably expected to be effective in inactivating the same virus.

Pamukoff provides an additional motivation to combine the composition of Pamukoff and Yu et al. to form a glycolic acid-ethanol-containing composition useful in the instant method. Both compositions are known to be useful in activating virus individually, it flows logically to combine these compositions useful for the very same purpose, absent evidence to the contrary (See *In re Kerkhoven* 205 USPQ 1069).

Claims 1 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatia et al. (Indian Journal of Animal Sciences 1998; 68(6): 518-520, reference of record) and Pamukoff (Canadian Patent: CA 122164, reference of record).

Bhatia et al. teaches that 0.4N hydrochloric acid is effective in inactivating sheep pox virus (See particularly page 519, col. 1, Table 1 and col. 2, third paragraph). Bhatia

et al. also teaches that the "Ranch" strain of goat pox virus is more sensitive in acidic pH 3.0 as there was 5 log fall in the titer in the acidic pH (See page 519, col. 2, third paragraph).

Pamukoff teaches that 1-10% ethyl alcohol containing composition for treating viral infections broadly, in particularly the infections that are caused by Herpes virus such as Herpes Simplex 1, Herpes Simplex 2, and common cold viruses (See particularly page 2, first paragraph; also page 7-9, Examples 2-5; also claims 1 and 2). Pamukoff also teaches that this antiviral composition can be formulated into creams (See particularly page 2, line 3).

The references do not expressly teach the herein claimed virus-inactivating method employing a composition comprises both ethanol and hydrochloric acid. The references do not expressly teach the pH of the composition used in the virus-inactivation method as 2.45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a composition comprises both ethanol and hydrochloric acid in a method for inactivating virus. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the pH of the composition to 2.45.

One of ordinary skill in the art would have been motivated to employ a composition comprises both ethanol and hydrochloric acid in a method for inactivating virus. Both the composition of Bhatia et al. and Pamukoff are known to be useful in inactivating virus individually. Therefore, it flows logically to combine the two

composition which are known to be useful to inactivate viruses individually into a single composition useful for the very same purpose is prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, optimization of the pH to 2.45 would be considered obvious as being within the purview of skilled artisan since the pH of the composition is essentially the amount of acid added. Absent showing evidence of the criticality of the specific amount of acid added, to adjust the effective amount f acid from pH 3.0 to 2.45 would be considered obvious as being within the purview of the skilled artisan.

As regard to the data showing synergistic results, they are not convincing (please see the discussion in the office action mailed October 22, 2002, page 8).

Response to Arguments

Applicant's arguments filed April 7, 2003 averring the amphoteric compounds, which are required to be in the composition in order to produce an pH of 2.45, being excluded by the claims as amended have been fully considered but they are not persuasive. As discussed in the rejections above, when the concentration of glycolic acid is about 0.31 M, the pH is about 2.5. 0.31M of glycolic acid falls within the range disclosed in Yu et al. Moreover, Yu et al. clearly disclosed that the amphoteric compounds are not necessarily present in the composition of Yu et al. in order to have antiviral activities (See col. 11, lines 55-59). The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic of the claimed invention.

For the purpose of searching for and applying prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.") (See MPEP 2111.03).

Applicant's rebuttal arguments file April 7, 2003 averring the presence of synergistic effects, i.e., unexpected benefits, have been considered, but are not found persuasive. The arguments have been addressed in the rejections above.

Applicant's arguments with respect to claims 1, 7, and 8 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617
June 27, 2003